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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,315

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Valentina Ivanovna Akhapkina

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,315	<b>Applicant(s)</b> AKHAPKINA ET AL.	
	<b>Examiner</b> Jennifer Kim	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/31/2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on January 31, 2008 has been entered.

Applicants' amendment necessitated of the new ground(s) of rejection presented in this Office action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 1, the claim provides for the **use** of N-carbamyl-methyl-4-phenyl-2-pyrrolidone, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

Art Unit: 1617

A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

However, to accelerate the prosecution of instant Application, claim 1 is interpreted as **“a method of treating depression comprising administering an effective amount of N-carbamyl-methyl-4-phenyl-2-pyrrolidone to a subject in need thereof”**.

With regard to claim 2, the claim recited “N-carbamyl-methyl-4-phenyl-2-pyrrolidone for use in the treatment of depression”. However, it is not clear if Applicants' are claiming N-carbamyl-methyl-4-phenyl-2-pyrrolidone as a **“composition”** or **“compound”**; or **“a method”** for treating depression comprising administering N-carbamyl-methyl-4-phenyl-2-pyrrolidone.

However, to accelerate the prosecution of instant Application, claim 2 is interpreted as **“a composition comprising N-carbamyl-methyl-4-phenyl-2-pyrrolidone for the treatment of depression”**.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Art Unit: 1617

However, to accelerate the prosecution of instant Application, claim 1 is interpreted as **“a method of treating depression comprising administering an effective amount of N-carbamoyl-methyl-4-phenyl-2-pyrrolidone to a subject in need thereof”**.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by INSTITUT MEDIKO-BIOLOGICHESKIKH PROBLEM et al. (RU 205051) of record.

INSTITUT MEDIKO-BIOLOGICHESKIKH PROBLEM teaches the use of N-carbamoylmethyl-4-phenyl-2-pyrrolidone (carphedon, also known as phenotropyl) as an agent with nootropic activity. (see also international search report).

The limitation of “treatment of depression” is noted. However, where the claimed invention is a chemical compound, the “compound and all of its properties are inseparable; they are one and the same thing”. In re Papesch, 315, F2d 381, 391 (C.C.P.A. 1963). In this case, the same active substance is taught by the reference. Therefore, the same active substance taught by the reference would inherently have the

Art Unit: 1617

properties of displaying antidepressant activity. The reference clearly anticipates the claimed substance. It discusses the same chemical compound. It must possess the same properties as claimed because it is one and the same compound.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Applicants' admission.

Applicants admit that phenotropyl (also known as N-carbamoylmethyl-4-phenyl-2-pyrrolidone) is known as a substance having nootropic activity taught in RU2050851. (see specification page 2, lines 9-12).

The limitation of "treatment of depression" is noted. However, where the claimed invention is a chemical compound, the "compound and all of its properties are inseparable; they are one and the same thing". In re Papesch, 315, F2d 381, 391 (C.C.P.A. 1963). In this case, the same active substance is taught by the reference. Therefore, the same active substance taught by the reference would inherently have the properties of displaying antidepressant activity. The reference clearly anticipates the claimed substance because it discloses the same chemical compound with properties inseparable as claimed from that compound.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

***Claim Rejections - 35 USC § 103***

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Differding et al. (WO 01/62726A2).

Art Unit: 1617

Differding et al. teach that 2-oxo-1-pyrrolidine derivatives of formula (I) including 2-(2-oxo-4-phenyl-pyrrolidinyl)acetamide (also known as N-carbamoylmethyl-4-phenyl-2-pyrrolidone set forth in claim 1) is useful for the treatment of depression. ( page 67 compound 2, page 89 claims 1 and 33-36).

Differding et al. do not expressly exemplify the treatment of depression comprising administering N-carbamoylmethyl-4-phenyl-2-pyrrolidone set forth in claim 1.

It would have been obvious to one of ordinary skill in the art to employ any one of 2-oxo-1-pyrrolidine derivatives of formula (I) including N-carbamoylmethyl-4-phenyl-2-pyrrolidone set forth in claim 1 because Differding et al. teach that the 2-oxo-1-pyrrolidine derivatives of formula (I) including 2-(2-oxo-4-phenyl-pyrrolidinyl)acetamide (also known as N-carbamoylmethyl-4-phenyl-2-pyrrolidone is effective for the treatment of depression and because such derivatives are equivalents and the effectiveness of antidepressant activity is retained. One would have been motivated to make such modification in order to achieve an expected benefit of treating depression in a patient suffering from such disorder with N-carbamoylmethyl-4-phenyl-2-pyrrolidone taught to be effective in treating depressive disorder in view of Differding et al.

None of the claims are allowed.



### **Response to Arguments**

Applicants' arguments with respect to claims 1-2 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1617

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/  
Primary Examiner, Art Unit 1617

Jmk  
February 8, 2008